

REMARKS

The claim set of the present application has been selectively amended without changing the subject matter of the remaining claims to reflect the specific features of the tubes that 1) each has a length to width ratio of no more than one and 2) each includes a differential in compressive stress to strain ratio angularly about the cylindrical tube with the maximum ratio and minimum ratio being at about 90° to one another. The remaining claimed subject matter has been cancelled from the application unless found depending upon recitations of the foregoing features.

All claims were rejected in the Official Action of February 9, 2005. By this amendment, claims 2 through 7, 12 through 14, 16, 17, 20 through 24, 26 and 27 are cancelled. Claims 7 and 27 have been made independent through addition to claims 1 and 25, respectively. Depending claims have been amended to retain proper dependency. The subject matter of the remaining claims has, therefore, not been narrowed.

Rejection Under 35 U.S.C. 112

The Official Action raises objection to claims 1, 25 and 27 noting that the length to width ratio of no more than unity is not shown in the drawings, that Figure 9 only shows one set of tubes and that there is lack of clarity as to whether the sets or the tubes vary in major cross-sectional dimension.

Each of Figures 2, 3, 5, 7, 8, 9, 11 and 12 show a length to width ratio of no more than unity. Taking Figure 7 as an example, the width can be measured, where there is no foreshortening, horizontally across the middle as being 3/4" while the height of the

wall as measured in the front of the Figure is $3/8$ ". Therefore, the length to width ratio is 0.5, well less than unity in this example.

Regarding the sets of tubes, Figure 9 is irrelevant to the issue. Figure 4 shows two sets of tubes. Reference is made to the second sentence in paragraph [0036] of the Specification.

Regarding the lack of clarity as to the reference to variation in the major cross-sectional dimension, note that the tubes are consistently referred to as cylinders. See line 2 of claim 1. Further, it is the sets that are described as having tubes with variation. A cylinder is a form which may not be circular in cross section but it is not conical or tapered along its length as a straight line which moves in a closed loop parallel to another line to generate a cylinder cannot create a taper. All illustrations also show the tubes to be cylinders, with only Figures 6 and 8 also showing special surface treatment.

Claim 25 was additionally rejected under 35 U.S.C. 112 as unclear as to the step of selecting one set or one tube. Claim 25 recites "selecting one from a plurality of tubes" with no mention of the "set" and additionally recites that "the one tube" is inserted in direct reference to that which was selected. Reading the selecting step as being of a set is inconsistent with the language in the claims and the specification. Additionally, even if a forced construction is of a "set" as well as of the one tube, the claim is simply broader and not indefinite. This effectively answers the inquiry regarding claim 27 as well, the subject matter of which has been incorporated into independent claim 25.

Given the aforementioned drawing features and recitations, reconsideration of the rejection of claims 1, 25 and 27 under Section 112 is requested.

Rejections Under Prior Art

Again, the claims reflect the specific features of the tubes that 1) each has a length to width ratio of no more than one and 2) each includes a differential in compressive stress to strain ratio angularly about the cylindrical tube with the maximum ratio and minimum ratio being at about 90° to one another. The applied patents do not have the recited ratio of length to width and do not teach a differential in compressive stress to strain ratio as recited in the present claims. Each feature must be found in the art to satisfy a *prima facie* case of obviousness. See MPEP § 2142, stating in part:

ESTABLISHING A *PRIMA FACIE* CASE OF OBVIOUSNESS

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. *Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.* The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP § 2143 § 2143.03 for decisions pertinent to each of these criteria.

[emphasis added]

The two enumerated features of the claims as not asserted in the Official Action to be shown in the prior art. Rather, these features are asserted to be matters of design choice on the basis that no criticality is shown in the specification. Relying on criticality without showing these claim limitations is inconsistent with the standard for a *prima facie* case of obviousness as presented in MPEP § 2142. Additionally, criticality regarding these two features is presented.

With regard to the feature of the ratio of length to width, reference is made to the discussion in the Background in paragraphs [0006] through [0009] where difficulties with longer tubes are discussed:

[0006] Certain of the tubular form types are applied by being inserted deeply into the nasal cavity so that the bottom of the tube is basically flush with the bottom opening of the nostril. The human nose structure, illustrated in Figure 1, around the immediate nostril opening is surrounded by the septum, intermediate crus, sesamoid cartilage and lower lateral cartilage - lateral crus. This area is generally elastic and fleshy with the exception of the lower lateral cartilage above the opening of the nostril. The lower lateral cartilage is connected only to the fleshy membrane around it. It is not connected directly to the rigid cartilage members above that give the rhinion area of the outer nose its distinctive shape.

[0007] Above the lower lateral cartilage is the upper lateral cartilage separated only by the intranasal suture line connected to the rigid nasal bone above. Any tubular nasal dilator device designed to be inserted deeply enough to potentially affect the upper lateral cartilage has a different function. It is this area where many individuals suffer a collapse of the generally narrowing airway. However, it is this area that is also most sensitive to manipulation by an external device protruding within. Many individuals have a deviated septum or other anomaly that affects sensitivity to this area. It can be painful to have this area manipulated by direct force expansion.

[0008] Such elongate devices may not be inserted so deeply as to physically engage the upper lateral cartilage. Such tubes as illustrated in the prior art are of a length to width ratio to substantially protrude below the lower nostril area if not placed so deeply. It was found through testing that any tube device, or connecting members such as tie straps, that protrudes substantially below the nostril area can easily be dislodged or repositioned during sleep.

[0009] It is common during sleep to touch the face or affect the nose area with contact of the pillow during sleep movement. A device that protrudes substantially below the lower nostril area can potentially be dangerous. Sleep movement can be violent at times when sleep is troubled. It is possible to hit this area of the nose with sufficient force to drive the dilator further up the nasal canal than intended. This can cause pain and potentially damage. There is also an increased potential for damage if the worn device protrudes substantially below the nostril during sports activities.

The criticality of the reduced length to width ratio is then discussed in paragraphs [0033] through [0035]:

[0033] The relationship of the length to width of the tube 16 allows it to be positioned in a normal nose without extending into the nasal passage 14 so far as to be adjacent the upper lateral cartilage 10. At the same time, the tube 16 does not extend substantially from the nasal passage 14. Such placement is illustrated in Figure 3. The tube 16 expands the region within which it is positioned in the nasal passage 14. The lower lateral cartilage 12 is able to move such that pressure on the delicate areas of the upper nasal passage will not be impacted by compression between the tube 16 and the lower lateral cartilage 12. Such would not be the case if the tube 16 extended into adjacent the upper lateral cartilage 10. Consequently, the ratio of length to width of the tube 16 being equal to or less than unity avoids the difficulties associated with insertion into adjacent the upper lateral cartilage 10.

[0034] At the same time, the placement of the tube 16 in the lower lateral area of the nostril cavity and its expansion of the soft tissue surrounding also acts to draw the soft tissue adjacent to the upper lateral cartilage 10 forwardly and outwardly to open up the nasal passage adjacent to the upper lateral cartilage 10, beyond where the tube 16 extends. Thus, a clear passage is created in the nasal passage 14 both adjacent the lower lateral cartilage 12 through the hole 20 in the nasal dilator tube 16 and past the upper lateral cartilage 10 through the influence of the tube 16 on the soft tissue in that area.

[0035] The length of the tube 16 also provides for the tube not extending substantially from the end of the nasal passage 14. This is advantageous because there is a tendency for the bedding or human contact to engage or otherwise interfere with tubing which extends from the nose. This can result in dislodging the tube from the nose or injuring the nasal soft tissue if abruptly impacted.

With regard to criticality of the differential stress/strain ratio, reference is made to the discussion in the Specification at paragraphs [0039] through [0041]:

[0039] Figure 7 illustrates yet another embodiment with a nasal dilator tube 36 having a hole 38 therethrough. The tube 36 is again shown to be a right circular cylinder with a length to width ratio of no more than unity. A tube septum 40 extends diametrically across the hole 38 and is integrally formed with the tube 36. This septum 40 provides a differential compressive stress to strain ratio angularly about the tube 36. Compressing the tube parallel to the septum tube 40 is more difficult than compressing the tube perpendicularly to the septum 40. Thus, a maximum stress to strain ratio is experienced in alignment with the septum 40 while a minimum stress to strain ratio is perpendicular thereto.

[0040] The foregoing contemplates the tube septum 40 being sufficiently rigid to exhibit column strength. If the septum 40 is thin, the maximum stress to strain ratio may be accomplished at 90° to the tube septum 40

instead where the septum 40 acts in tension. This property may be thought of also as a differential effective width as the user perceives that the nasal dilator 36 is wider or narrower depending on its orientation given the stress to strain ratios.

[0041] Employment of the embodiment of Figure 7 provides for insertion of the tube 36 into longitudinal position within the nasal passage 14. Rotation of the nasal dilator 36 then provides for increased soft tissue distortion in whichever way a greater opening requirement is desired, typically with the maximum resistance to compression being oriented laterally within the nose.

Each feature is specifically discussed as to its specific criticality. The recited features are not simply matters of design choice.

So as to avoid any prospect of estoppel, applicant also notes that the reference of Wang has ribs and does not have septums. A septum divides chambers, forms a partition. The ribs do not form partitions or divide chambers. Again, the references fail to support a *prima facie* case of obviousness.

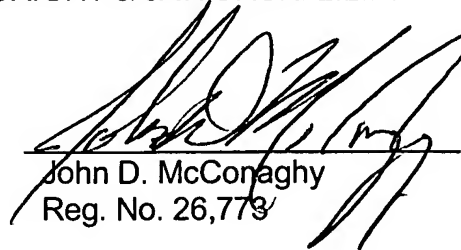
In view of the foregoing changes to focus the claims and the presentation of supporting text and drawing to support and clarify the claims and to establish criticality, reconsideration of the rejections is requested. A notice of allowance is earnestly solicited.

Respectfully submitted,

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